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10/725,233	12/01/2003	Irene Quenville	P03346	2124
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Bausch & Lomb Incorporated One Bausch & Lomb Place Rochester, NY 14604-2701			EXAMINER DELCOTTO, GREGORY R	
			ART UNIT 1796	PAPER NUMBER
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/725,233

Applicant(s)

QUENVILLE ET AL.

Examiner

Gregory R. Del Cotto

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 September 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3 and 5-7 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3 and 5-7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. Claims 1, 3, and 5-7 are pending. Applicant's arguments and amendments filed 9/12/07 have been entered. Claims 2, 4, and 8-17 have been canceled. Note that, at the outset, it is noted that claim 1 has been amended such that 1,1' hexamethylene-bis[5(2-ethylhexyl)biguanide has been replaced by poly(hexamethylene biguanide) (PHMB) as the antimicrobial agent.

### **Objections/Rejections Withdrawn**

The following objections/rejections as set forth in the Office action mailed 6/12/07 have been withdrawn:

The rejection of claims 1-4 and 6 under 35 U.S.C. 103(a) as being unpatentable over Asgharian et al (US 6,228,323) in view of Huth (US 6,165,954) or Heiler et al (US 6,323,165) has been withdrawn.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

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the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3, and 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Groemminger (US 2002/0115578) in view of Asgharian et al (US 6,228,323).

'578 teaches an aqueous composition for cleaning and wetting a contact lens containing a non-amine polyethyleneoxy-containing material having an HLB value of at least about 18, a first non-ionic surface active agent having cleaning activity for contact lens deposits that comprises a poloxamine, a second non-ionic surface active agent, and wetting agent. See Abstract. The cleaning compositions also include buffering agents such as sodium carbonate. Also, the compositions may contain antimicrobial agents in amounts from 0.00001 to about 5% by weight. Suitable antimicrobial agents include polyhexamethylene biguanide, etc. See para. 23-26. The compositions may also contain a sequestering agent such as EDTA.

Groemminger does not teach the use of a polyethyleneterephthalate container, or an article of manufacture comprising a container formed from polyethyleneterephthalate and a composition containing surfactants, poly(hexamethylene biguanide) as an antimicrobial agent, and the other requisite components of the composition in the specific amounts as recited by the instant claims.

Asgharian et al teach a two-compartment bottle assembly useful in preparing multi-purpose compositions containing an Al-trypsin and disinfectant. These compositions are useful for cleaning and disinfecting contact lenses. See Abstract. The bottle may be made out of materials such as molded polyethylene, polyethyleneterephthalate (PET), etc. See column 5, lines 1-5. The disinfecting compositions generally contain one or more antimicrobial agents, a buffer, tonicity agents, a chelating agent, and surfactants (i.e. block copolymers). See column 11, lines 50-69. Specifically, Asgharian et al contain cleaning compositions containing 0.001% Polyquaternium 1, 0.6% boric acid, 0.1% sodium chloride, 0.05% Tetronic 1304, 0.05 disodium edetate, water, etc. See column 14, lines 25-45.

Asgharian et al are relied upon as set forth above.

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to package the compositions taught by Groemminger in a polyethyleneterephthalate container, at the time the invention was made, because Asgharian et al teaches the use of a polyethyleneterephthalate container to package similar contact lens cleaning/disinfecting compositions.

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to formulate an article of manufacture comprising a container formed from polyethyleneterephthalate and a composition containing surfactants, poly(hexamethylene biguanide) as an antimicrobial agent, and the other requisite components of the composition in the specific amounts as recited by the instant claims, with a reasonable expectation of success and similar results with respect to other

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disclosed components, because the broad teachings of Groemminger in combination with Asgharian et al suggest an article of manufacture comprising a container formed from polyethyleneterephthalate and a composition containing surfactants, poly(hexamethylene biguanide) as an antimicrobial agent, and the other requisite components of the composition in the specific amounts as recited by the instant claims.

### ***Response to Arguments***

With respect to the rejection of the instant claims under 35 USC 103(a) using Groemminger in combination with Asgharian et al, Applicant states that experimental data has been presented that demonstrates the advantages of packaging a contact lens disinfecting solution that comprises the recited range of PHMB and one or more of the recited surfactants in a PET bottle compared to packaging the same solution in a HDPE bottle. In response, note that, the Examiner asserts that Applicant has provided the data as part of the attorney's arguments, which is not an appropriate means for submission of data attempting to show the unexpected and superior properties of the claimed invention. In fact, Applicant clearly states that this data was unfortunately not included in the application at the time of filing. Note that, objective evidence which must be factually supported by an appropriate affidavit or declaration to be of probative value includes evidence of unexpected results, commercial success, solution of a long-felt need, inoperability of the prior art, invention before the date of the reference, and allegations that the author(s) of the prior art derived the disclosed subject matter from the applicant. See, for example, In re De Blauwe, 736 F.2d 699, 705, 222 USPQ 191, 196 (Fed. Cir. 1984). Additionally, the arguments of counsel cannot take the place of

evidence in the record. In re Schultze, 346, F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965). Examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration include statements regarding unexpected results, commercial success, solution of a long-felt need, inoperability of the prior art, invention before the date of the reference, and allegations that the author(s) of the prior art derived the disclosed subject matter from the applicant. See MPEP 716.01(c). The Examiner asserts that in order to be persuasive, any data presented attempting to show evidence of unexpected results must be in the form of an appropriate affidavit or declaration. Thus, the data presented as part of the attorney's arguments in the instant case is moot and has not been considered, and the rejection of the instant claims under 35 USC 103(a) using Groemminger in combination with Asgharian et al has been maintained.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any




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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory R. Del Cotto whose telephone number is (571) 272-1312. The examiner can normally be reached on Mon. thru Fri. from 8:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon can be reached on (571) 272-1498. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Gregory R. Del Cotto  
Primary Examiner  
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GRD

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November 25, 2007